Board of Pharmacy

Final Statement of Reasons

Subject Matter of Proposed Regulation: Pharmacies and Wholesalers; Self-Assessment

Title 16 Sections Affected: Amend 16 Cal. Code Reg. § 1715
Amend 16 Cal. Code of Regs § 1735.2
Amend 16 Cal. Code of Regs § 1751, and
Amend 16 Cal. Code of Regs § 1784

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding the adoption of the above sections, but is updated to include the following information. The board's notice indicated that the board did not intend to hold a hearing on the matter, unless requested. No request for hearing was received by the board.

Recommendations and comments received during the 45-day public comment period from March 11, 2011 to April 25, 2011 were considered by the Board at its May 3, 2011 meeting. The Board's responses to the comments received are detailed under "Summary of Comments Received During the 45-Day Comment Period". After reviewing the comments, the Board voted to adopt the originally noticed text with only non-substantial or grammatical changes to the original text.

Those non-substantial changes are described as follows:

To correct a typographical error, item number 5. of the Underlying Data is hereby amended to read "Senate Bill ***819***, Chapter ***308***, Statutes of 2009 (not Senate Bill 795, Chapter 307).

As described in the Initial Statement of Reasons (page 2), "bullets" were added throughout the document to items in a list that are indented below an opening sentence or paragraph to provide for easy separation and reading. In the final version of each form incorporated by reference, and in response to comments received during the 45-day public comment period, these bullets were changed from closed circular bullets, to open square bullets. This change allows a person completing the form to use the bullet as a "check off" box if so desired. This change is deemed to be without regulatory effect because it is revising the format of the punctuation in the document and does not alter the content of the proposal.

As explained in the response to comments, the board modified each of the forms incorporated by reference to add sequential numbering of items / sub-items so that information on a self-assessment form could be more easily referenced or identified. For example, in Section 6 of the Compounding Self-Assessment (17M-39 (Rev. 01/11), page 6), four items are listed. To provide easy reference to the items, the items were

sequentially numbered: 6.1, 6.2, 6.3, and 6.4. The board believes this type of change is without regulatory effect, as the changes reflect the ordering or numbering of items within a form, and does not modify the substantive text in any way.

Additional changes without regulatory effect have been made to forms incorporated by reference, as itemized below:

Form 17M-13 "Community Pharmacy Self-Assessment, Hospital Outpatient Pharmacy Self-Assessment"

In Section 1, sub-item 1.10, the cross-reference to the section on Compounding was corrected to read "**section 24 – "Compounding**" (not section 23). This provides an accurate cross-reference to the section that addresses compounding (as found on page 20 of the form). This change is believed to be non-substantial because it revises a cross-reference found in the form.

Form 17M-14"Hospital Pharmacy Self-Assessment"

In Section 20 related to Emergency Room Dispensing, sub-item 20.7. the word "progesterone" and the related reference to 16 CFR 310.516, was removed. As identified in the Initial Statement of Reasons (see Underlying Data, item 11), the applicable federal regulation (21 CFR 310.516) was repealed effective November 16, 2000. As initially noticed, this same reference was stricken from Section 21 (sub-item 21.13) but was overlooked in Section 20 at initial notice. The board believes this change is without regulatory effect because the federal statutory authority related to this item has been repealed and the board is updating a reference.

As explained in the response to comments, as proposed, the sixth sub-item in Section 21 was a "garbled" printing of a portion of the item before, and the item after. This mis-printed text was not included in the previously approved version of the form, and it was stricken from the final form. This change is considered to be without regulatory effect because it was a mis-print that comprised components of the prior and following items.

In Section 22, item 22.2., a formatting line was added to provide an area in which information could be written on the form in response to the question stated. This change is considered to be non-substantial because it is only a formatting change.

In Section 23, at the end of each sequentially numbered sub-item, the ending punctuation was changed from "semi-colons" to "periods." This formatting and punctuation change is consistent with Underlying Data as identified in the Initial Statement of Reasons (Underlying Data, item 13.). Also, at the end of item 23.1.5, a closing parenthesis was stricken from the end of the sentence, as it was unnecessary.

Form 17M-26 "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment"

In item 12 (page 14) the line spacing of sub-items 12.1.1. to 12.1.12. was adjusted (fractionally increased) so as to eliminate crowding of the sequentially numbered sub-items and provide for easier readability. This change is considered to be non-substantial because it is adjusting the formatting / line spacing in the document.

Form 17M-39 "Compounding Self-Assessment"

To correct a typographical error, item 4.4. (page 5), a reference cited as B&PC 4075.4[d] was corrected to read B&PC ***4076.5[d]***.

Following item 19 (page 14), the words "(Continued on Next Page)" were inserted to indicate to the reader that the form continued on the following page. This mirrors the text found on page 7 of the document, where more than one third of the page is blank, and the phrase was added to aid the reader that the form continued on the next page. This change is considered to be non-substantial because it relates to the formatting of the document and provides clarity to the reader that the form is continued on the following page.

Local Mandate:

None.

Business Impact:

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of comments or testimony indicating adverse economic impact regarding this rulemaking proposal.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to the affected persons than the proposed regulation.

Summary of Comments Received During the 45-Day Comment Period (Objections or Recommendations/Responses):

The board received comments from four individuals during the 45-day public comment period, as follows:

Comment from William J. Blair, PharmD, MBA

Dr. Blair commented on the self-assessment form entitled "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" (Form 17M-39, Rev. 01/11) which is incorporated by reference in 16 CCR § 1715. Dr. Blair objects to the proposed added text which references the requirements of 16 CCR §1707.5(a), where – if requested by the patient – a prescription label is printed in 12-point typeface.

Dr. Blair further objects to the proposed added text which references Business & Professions Code § 4076.5, which would indicate whether or not the pharmacy is exempt from the prescription label requirements of 16 CCR § 1707.5.

Dr. Blair comments that the two proposed additions do not refer to the labeling of compounded drug products and should be removed. He further comments that placing these references in the section addressing the "labeling of compounded drug products" confuses the product label requirements and should be excluded.

Board Response

The board does not agree with the comments made by Dr. Blair regarding the proposed additions to item 4 of the "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" (Form 17M-39, Rev. 01/11), identified as sub-items 4.3 and 4.4.

Board regulations found at Title 16 Cal. Code of Regs § 1707.5 (operative on 1/1/2011) specify the requirements for labels on prescription drug containers dispensed to patients in California. In part, this regulation specifies a minimum typeface of the label, the order in which specified information is to be printed on a label, and also specifies that if requested by the consumer, the label shall be printed in at least a 12-point typeface. If the pharmacy dispenses a drug to a patient in California, the labeling of the drug product is required to comply with the board's regulation. The regulation does not specify that compounded drug products are exempt.

Business and Professions Code section 4076.5 mandated that the board promulgate regulations to establish a patient-centered prescription drug label on all prescription medications dispensed to patients in California. The statute was added by Chapter 470, Statutes of 2007. In 2010, the statute was amended (see Chapter 653, Statutes 2010) to provide the board with the authority to grant exemptions from the patient-centered drug label requirements (i.e., 16 CCR 1707.5), as specified. If the compounding pharmacy met the criteria for exemption under Business and Professions Code section 4076.5, and subsequently requested and received board

approval to be exempt from the patient-centered prescription drug labeling requirements, then the pharmacy completing the self-assessment form would utilize the "N/A" box to check that the item is not applicable. However, if the compounding pharmacy dispensed compounded prescription drugs to patients, then the requirements of the board's regulation at 16 CCR 1707.5 would apply. For these reasons, the board did not feel that the proposal should be amended to eliminate the proposed text and provide modified text for additional public comment.

Comments from Dave Halterman, Pharm.D.

Dr. Halterman provided comment on four items found in Section 21 of form 17M-14. Form 17M-14 is entitled "Hospital Pharmacy Self-Assessment" and is incorporated by reference in 16 CCR 1715(c).

#1. Regarding the second item under Section 21, which currently reads "Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)"

Dr. Halterman comments *"using the word 'another' implies that the prescription will be transferred between two pharmacies. However B&PC 4072 actually references any appropriate health care provider transmitting the prescription and, I believe, is the basis for the intent of this particular item. Dr. Halterman suggest that if the word 'a' was substituted for the word 'another' the item would more accurately reflect the cited references."*

Board Response

This comment is not specifically directed at the board's proposed action or to the procedures followed by the board, as the board's rulemaking did not propose any modifications to item two under Section 21 of Form 17M-14. The board reviewed all comments at its May 3, 2011, Board Meeting and did not move to modify the text of the proposed rulemaking, or the text of the forms incorporated by reference, in response to this comment.

#2. Regarding Section 21, line items 3 – 6, and line items 8 – 12, which reference packaging and labeling requirement of outpatient prescriptions.

Dr. Halterman comments these items *"are specifically referencing packaging and labeling requirements of outpatient prescriptions. Since a hospital can only package an outpatient prescription if it has an Outpatient Hospital Pharmacy, the hospital will be required to complete form 17M-13. If that is the case, these exact line items are in that form and this would be duplicative work. If the intent of these items is to also apply to Emergency Room Dispensing, this information is already covered in section 20 of form 17M-14 and is also duplicative. Either way, there is no point in these line items on this form as any hospital that would answer them 'Yes' would have to answer them on another form and if they answer them 'N/A', it will be N/A*

for all of them because the service is not even within the scope of the hospital pharmacy."

Board Response

The board appreciates Dr. Halterman's comments, but disagrees with this comment. Relative to line items 3 – 6, the board infers that Dr. Halterman objects to the proposed added text that references the requirements of 16 CCR 1707.5. Effective January 1, 2011, and pursuant to Business and Professions Code section 4076.5(a), the board promulgated regulations to establish requirements for standardized, patient-centered, prescription drug labels. Also, subdivision (d) of B&PC 4076.5 specifies that prescriptions that are provided to the patient upon discharge from a facility (as defined in Section 1250 of the Health and Safety Code) are subject to the requirements of the section and to the regulations promulgated by the board relative to a standardized, patient-centered, prescription drug label. As such, it is appropriate that the Section 21 of form 17M-14 ("Discharge Medication/ Consultation Services") reference the statutory and regulatory provisions that apply to medications provided to patients upon discharge from the facility. Thus, the board did not move to modify the text of the proposed rulemaking, or the text of the forms incorporated by reference, in response to this comment.

Relative to line items 8 – 12, that reference packaging and labeling of outpatient prescriptions, the board did not propose any modifications to those items in its rulemaking. The board reviewed all comments at its May 3, 2011, Board Meeting and did not move to modify the text of the proposed rulemaking, or the text of the forms incorporated by reference, in response to this comment.

#3. Regarding Dr. Halterman's comment: *"Line item 5 is complete garbled."*

Board Response

The board appreciates Dr. Halterman's comment. This line item is a typographical error, and did not appear on the form version previously approved by OAL. It appears that in the printing of the proposed form, a portion of the prior line item, combined with a portion of the line item that followed, had combined to reflect an item that is completely "garbled." During the board's May 3, 2011, Board Meeting, the board directed that the rulemaking be adopted, and that typographical and/or non-substantive corrections are made to the text and forms. As directed, staff has stricken this "garbled" typographical error from Form 17M-14.

#4. Regarding Section21, line item 7 which currently reads: "Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)"

Dr. Halterman comments that the item *"is appropriate based on the articles cited, but is vague and, in my opinion, would be better worded to reflect section 4074(d): "A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each medication given at the time of discharge…."*

Board Response

The board appreciates Dr. Halterman's comment but disagrees that the item should be modified in response to the comment. The board did not propose any modifications to this line item in its rulemaking. Business and Professions Code section 4074(a) requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription, as specified. Subdivision (d) speaks specifically to the requirement that a health facility establish and implement a written policy to ensure that each patient receives information regarding each medicine at the time of discharge. The board reviewed all comments at its May 3, 2011, Board Meeting and did not move to modify the text of the proposed rulemaking, or the text of the forms incorporated by reference, in response to this comment.

Dr. Halterman provided comment on the proposed added text (final bullet point) to Section 23 ("Policies and Procedures").

#5. Dr. Halterman states that this proposed added text is duplicative if the hospital pharmacy also has to complete Form 17M-13, Community Pharmacy & Hospital Pharmacy Outpatient Form. He adds that if the hospital pharmacy is not required to complete Form 17M-13, the citation does not apply (to 17M-14) and the proposed added text is not an appropriate entry for the inpatient facility self-assessment.

Board Response

Effective January 1, 2011, and pursuant to Business and Professions Code section 4076.5(a), the board promulgated regulations to establish requirements for standardized, patient-centered, prescription drug labels (see 16 CCR 1707.5). Subdivision (d) of 16 CCR 1707.5 specifies that *the pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label,* as specified. B&PC section 4076.5(d) further specifies that prescriptions that are provided to the patient upon discharge from a facility (as defined in Section 1250 of the Health and Safety Code) are subject to the requirements of the section and to the regulations promulgated by the board relative to a standardized, patient-centered, prescription drug label. As such, board regulations at 16 CCR 1707.5(d) relative to the policies and procedures required to help patients with limited or no English proficiency understand the information on the label, is applicable in the inpatient setting, and that this reference included in Section 23 of Form 17M-14 is an appropriate reference. The board reviewed all comments at its May 3, 2011, Board Meeting and did not move to modify the text of the proposed rulemaking, or the text of the forms incorporated by reference, in response to this comment.

Comment by Narinder Singh, Pharm.D., MBA

Dr. Singh proposed to add text to the "Pharmacist-in-Charge section of ALL the Self-Assessment documents." He referenced text that is found in Form 17M-14, item 5.2. Though not specifically stated, a like reference is also found in

Form 17M-13, item 4.2. He recommends adding the phrase *"skills, knowledge, and training"* to each of these sections.

Board Response

The board appreciates Dr. Singh's comment; however, his comments are not specifically directed at the board's proposed action, in that the board did not propose any modifications to the references addressed by Dr. Singh in its proposed action. Business and Professions Code section 4036.5 defines "Pharmacist-in-charge" as a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. The board believes existing statute clearly defines the requirements for a pharmacist-in-charge, and that the existing references in the form do not require modification. The board reviewed all comments at its May 3, 2011, Board Meeting and did not move to modify the text of the proposed rulemaking, or the text of the forms incorporated by reference, in response to this comment.

Comment by Steven W. Gray, Pharm.D., JD, Kaiser Permanente

Dr. Gray commented that throughout each self-assessment form, it would be helpful for each sub-item within a topic/item to have a reference number or an indicator so that a person could quickly identify a particular sub-item.

In addition, Dr. Gray indicated that he felt it was important that each item/question/statement should have its own set of "boxes" so that the person completing the form could indicate the level of compliance with each separate statement or item. Dr. Gray indicated these changes were needed if an owner or a designated representative is required to sign the self-assessment form.

Board Response

In response to Dr. Steve Gray's comments, the board in its motion to adopt the regulation and the forms incorporated by reference directed staff to include any non-substantive changes, such as the formatting and sequential numbering of items as described by Dr. Gray in his comment. As a result, the following formatting changes were made to each of the forms incorporated by reference:

- To provide for easy reference or identification of items within a question / section, sequential numbering was added to sub-items. For example, in Section 6 of the Compounding Self-Assessment (17M-39 (Rev. 01/11), page 6), four items are listed. To provide easy reference to the items, the items were sequentially numbered: 6.1, 6.2, 6.3, and 6.4. The board believes this type of change is non-substantial, as the changes reflect the ordering or numbering of items within a form.
- Throughout the forms, an item has a set of three boxes so that the person completing the form could indicate the level of compliance (i.e., "Yes No N/A") with an item or question. Where sub-items are listed, the board proposed

closed circular bullets. In response to this comment, the board modified the shape (format) of the "bullets" from a closed circular bullet to an open square bullet. This format change allows a person completing the form to use the bullet as a "check off" box if so desired. The board believes this change is non-substantial or grammatical because it is revising the punctuation or formatting in the document and does not alter the content of the proposal.

The board determined that these changes were non-substantial as the changes were reflective of the ordering, numbering, or punctuation and formatting of items within each form, and did not substantively alter the content of the proposed text.